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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,571	03/22/2007	Ashley Martin Williams	85128-1202	4852

7590 07/21/2009

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EXAMINER	
STOICA, ELLY GERALD	

ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
07/21/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/573,571	WILLIAMS ET AL.	
	Examiner	Art Unit	
	ELLY-GERALD STOICA	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the claims

1. Claims 1-15 are pending and are currently examined.

Claim Objections

2. Claims 3 and 7 are objected to because of the following informalities: it appears that in the second line of each of the claims, after “glycol”, the word ‘concentration’ is missing. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-12 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the independent claim 1, the wording "an effective amount of Polyethylene glycol" is indefinite since the formulation is not a pharmaceutical and there is no intended use claimed. T is not clear what function is to be imparted by the PEG. Thus the metes and bounds of the claims could not be determined. The claims 2-12 and 15 are rejected as dependent claims.

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Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 2 are rejected under 35 U.S.C. 102(e) as being anticipated by Govardhan et al. (US20040209804, filed 12/31/2003 and claiming priority to 60/437519, filed 12/31/2002).

Govardhan et al. teach stable, long-acting, pharmaceutically acceptable (i.e. sterile) composition comprising human growth hormone. The compositions of this invention are advantageously used in methods for treating an individual having a disorder associated with human growth hormone deficiency or which is ameliorated by treatment by treatment with human growth hormone [0014]. One of the reagents comprised in the composition is polyethylene glycol (PEG). The PEG has a molecular weight between about 200 and about 8000. The PEG is present at a concentration between about 0.5% and about 12% w/v ([0092]), which would include the range limits claimed in the instant Application. The hGH concentration may be between about 0.1 mg/ml and about 100 mg/ml. Such compositions also include the following components: mannitol (as a tonicifying reagent), Tris HCl--about 5 mM to about 100 mM (as a buffering system); pH about 6.0 to about 9.0 (preferably about 6.5 to about

8.5); PEG (MW 800-8000, preferably 3350, 4000, 6000 or 8000)-0 to about 25% ([0084]).

Thus, the claims 1 and 2 are anticipated by Govardhan et al.

Claim Rejections - 35 USC § 102/103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 3-15 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Govardhan et al. (US20040209804, filed 12/31/2003 and claiming priority to 60/437519, filed 12/31/2002).

As presented above, Govardhan et al. teach stable, long-acting, pharmaceutically acceptable (i.e. sterile) composition comprising human growth hormone. The compositions also comprise preservatives (antimicrobial, phenol, metacresol, benzyl alcohol, parabenzoate (paraben))--0% to about 5% [0084]. Which are used as antimicrobial agents. The compositions may also contain boric acid (which was known in the art as a chelating agent-evidentiary reference- Hakoila et al., Chelation of Boric Acid with Nitropyrocatechols and the Photometric Determination of Boric Acid, Anal. Chem. 44, 1857-1860, 1972, cited as evidence only, and not as part of this rejection.). It is submitted that the properties of the composition are dictated by its components and, even though Govardhan et al. do not mention the stability of their

combination after long term cold storage, the composition being the same it would behave the same as in the instant Application. The compositions of this invention are advantageously used in methods for treating an individual having a disorder associated with human growth hormone deficiency or which is ameliorated by treatment with human growth hormone ([0014]). The composition is injected in the patient in need ([0059]).

Since the Office does not have the facilities for examining and comparing applicants' formulation with the formulation of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the formulation of the prior art does not possess the same material structural and functional characteristics of the claimed formulation). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

Moreover, because as stated above, no specific amount were specified in the claims, it would have been obvious for a person of ordinary skill in the art at the time that the invention was made to reach the formulations claimed in the instant Application by using the teachings of Govardhan et al. and using the known agents so as to achieve the most stable storing life possible.

Conclusion

8. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELLY-GERALD STOICA whose telephone number is (571)272-9941. The examiner can normally be reached on 9:00-18:30 M-Th and 9:00-18:30 alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lorraine Spector/

Primary Examiner, Art Unit 1647